

Synthes Spine 510(k) Premarket Notification
USS Line Extension
JUN - 6 2001

3.0 Summary of Safety and Effectiveness Information

SPONSOR: Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700
Contact: Jonathan Gilbert

DEVICE NAME: USS- Line Extension

CLASSIFICATION: The classification of the USS Line Extension components is Class II, as per the Code of Federal Regulations, Title 21, Section 888.3070: Pedicle Screw Spinal System. The product code is KWP. The Panel code is 87.

PREDICATE DEVICE: Synthes USS (K003061 and K990745)

DEVICE DESCRIPTION: The subject USS components consist of longer length side-opening screws of various thread lengths and shaft types. The screws are designed to be affixed to the thoracic spine, lumbosacral spine and/or ilium using previously cleared spinal rods. This submission also amends previously cleared USS screws for use in ilium fixation

INTENDED USE: Posterior Components
When used as a posterior pedicle screw fixation system, the Synthes USS is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

In addition, the Synthes USS is intended for treatment of severe spondylolisthesis (grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the **lumbosacral spine and/or ilium** with removal of the implants after the attainment of a solid fusion. The levels of pedicle screw fixation for these patients are L3-S2 / **ilium**.

When used as a posterior non-pedicle screw fixation system, the Synthes USS is intended for scoliotic, lordotic, or kyphotic deformities (such as scoliosis, Schuermann's disease), degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), and fractures of the posterior thoracolumbar spine. **Overall levels of fixation are T1-sacrum/ilium.**

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INTENDED USE (cont): The CLICK'X and USS VAS components of the Synthes USS, when used as a posterior pedicle screw fixation system, are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal tumor and failed previous fusion (pseudoarthrosis).

In addition, the CLICK'X and USS VAS components of the Synthes USS are intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine with removal of the implants after the attainment of a solid fusion. The levels of pedicle screw fixation for these patients are L3-S2.

In addition, when used with 3.5/6.0 mm parallel connectors, the Synthes USS can be linked to the CerviFix System.

Anterior Components

The Anterior Components of the USS are intended for anterolateral screw and/or staple fixation for the correction of anterolateral lordotic deformities for the spine, lumbar scoliosis, pseudoarthrosis, and fracture or dislocation of the thoracolumbar spine (levels T8-L5).

MATERIAL: The subject components are made from titanium alloy Ti-6Al-7Nb (ASTM F1295).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2001

Mr. Jonathan Gilbert
Senior Regulatory Affairs Associate
SYNTHES
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301-1262

Re: K010108

Trade Name: USS-Line Extension
Regulation Number: 888.3070, 888.3050 and 888.3060
Regulatory Class: II
Product Code: MNI, MNH, KWP and KWQ
Dated: April 17, 2001
Received: April 18, 2001

Dear Mr. Gilbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "C. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.
Director

Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

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2.0 Indications for Use Statement

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510(k) Number (if known): K010108

Device Name: USS Line Extension

INDICATIONS:

Posterior Components

When used as a posterior pedicle screw fixation system, the Synthes USS is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

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Indications for Use Statement (continued)

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Anterior Components

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____